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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,221	01/02/2004	Kenneth K. Cyr	CRNL111422	6658
46169 7590 07/25/2008 SHOOK, HARDY & BACON L.L.P. Intellectual Property Department 2555 GRAND BOULEVARD KANSAS CITY, MO 64108-2613				
EXAMINER				
SEREBOFF, NEAL				
ART UNIT		PAPER NUMBER		
3626				
MAIL DATE		DELIVERY MODE		
07/25/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/750,221

Applicant(s)

CYR ET AL.

Examiner

NEAL R. SEREBOFF

Art Unit

3626

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 6/24/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant/ Response to Amendment

1. In the amendment dated 4/23/2008, the following has occurred: Claim 10 has been amended; Claim 13 has been canceled. Claims 1 – 12 and 14 - 27 are pending.
2. The Information Disclosure Statement dated 6/24/2008 has been considered.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

4. ***Claims 1 – 12 and 14 - 27*** are rejected under 35 U.S.C. 102(b) as being anticipated by Shalmi et al., U.S. Pre-Grant Publication Number 2002/ 0188469.
5. As per claim 1, Shalmi teaches a system for managing clinically related supply procurement according to outcomes, comprising:
 - A first interface to receive patient supply data captured from at least one clinically related site, the patient supply data comprising clinical supplies used to treat one or more patients (paragraph 53, manufacturer supply);
 - A second interface to receive clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies from the at least one clinically related site (paragraph 53, patient supply); and
 - An analytic engine, the analytic engine communicating with the first interface and the second interface to generate comparative clinical supply reports based at least on the clinical outcomes data (paragraph 53, needs analysis).

6. As per claim 2, Shalmi teaches the system of claim 1 as described above. Shalmi further teaches a system wherein the patient supply data comprises at least one of surgical device information, pharmaceutical information, and consumable material information (paragraph 53, pharmaceutical information).
7. As per claim 3, Shalmi teaches the system of claim 1 as described above. Shalmi further teaches a system wherein the clinically related site comprises at least one of a hospital facility, a research facility and a government facility (paragraphs 52 or 54, hospital).
8. As per claim 4, Shalmi teaches the system of claim 1 as described above. Shalmi further teaches a system wherein the clinical outcomes data comprises at least one of patient mortality data, patient morbidity data, patient ambulatory data, patient infection data, patient prescription data, patient length of stay data, patient condition data and patient readmittance data (paragraph 53, patient prescription data).
9. As per claim 5, Shalmi teaches the system of claim 1 as described above. Shalmi further teaches a system wherein the comparative clinical supply reports comprise historical patient outcome comparisons between alternative supply selections (paragraphs 66, 67 and 72, statistical analysis and usage analysis).
10. As per claim 6, Shalmi teaches the system of claim 5 as described above. Shalmi further teaches a system wherein the historical patient outcome comparisons are based on a combination of at least two supply selections (paragraph 72 – 74, price, time and quantity).
11. As per claim 7, Shalmi teaches the system of claim 1 as described above. Shalmi further teaches a system wherein the comparative clinical supply reports comprise projected patient

outcome comparisons based on alternative supply selections (paragraph 70 where usage information is kept to determine drug deployment).

12. As per claim 8, Shalmi teaches the system of claim 7 as described above. Shalmi further teaches a system wherein the projected patient outcome comparisons are based on a combination of at least two supply selections (paragraph 70, location and population or paragraph 71, price and duration or paragraph 72, usage based).

13. As per claim 9, Shalmi teaches the system of claim 1 as described above. Shalmi further teaches a system wherein the comparative clinical supply reports comprise reports on clinical outcomes data broken down according to at least one of clinical procedure type, clinical department, patient condition categories, patient demographic categories, vendor information and cost ranges (paragraphs 70 - 72, patient demographics and cost ranges).

14. As per claim 10, Shalmi teaches a method for managing clinically related supply procurement according to outcomes, comprising:

- Receiving patient supply data captured from at least one clinically related site, the patient supply data comprising clinical supplies used to treat one or more patients (paragraph 53, manufacturer supply);
- Receiving clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies from the at least one clinically related site (paragraph 53, patient supply), wherein the clinical outcomes data is patient condition data (paragraph 46, bleeding or paragraph 50, hemophilia or weight); and
- Generating comparative clinical supply reports based at least on the clinical outcomes data (paragraph 53, needs analysis).

15. As per claim 11, Shalmi teaches the method of claim 10 as described above. Shalmi further teaches the method wherein the patient supply data comprises at least one of surgical device information, pharmaceutical information, and consumable material information (paragraph 53, pharmaceutical information).

16. As per claim 12, Shalmi teaches the method of claim 10 as described above. Shalmi further teaches the method wherein the clinically related site comprises at least one of a hospital facility, a research facility and a government facility (paragraphs 52 or 54, hospital).

17. As per claim 14, Shalmi teaches the method of claim 10 as described above. Shalmi further teaches the method wherein the comparative clinical supply reports comprise historical patient outcome comparisons between alternative supply selections (paragraphs 66, 67 and 72, statistical analysis and usage analysis).

18. As per claim 15, Shalmi teaches the method of claim 14 as described above. Shalmi further teaches the method wherein the historical patient outcome comparisons are based on a combination of at least two supply selections (paragraph 72 – 74, price, time and quantity).

19. As per claim 16, Shalmi teaches the method of claim 10 as described above. Shalmi further teaches the method wherein the comparative clinical supply reports comprise projected patient outcome comparisons based on alternative supply selections (paragraph 70 where usage information is kept to determine drug deployment).

20. As per claim 17, Shalmi teaches the method of claim 16 as described above. Shalmi further teaches the method wherein the projected patient outcome comparisons are based on a combination of at least two supply selections (paragraph 70, location and population or paragraph 71, price and duration or paragraph 72, usage based).

21. As per claim 18, Shalmi teaches the method of claim 10 as described above. Shalmi further teaches the method wherein the comparative clinical supply reports comprise reports on clinical outcomes data broken down according to at least one of clinical procedure type, clinical department, patient condition categories, patient demographic categories, vendor information and cost ranges (paragraphs 70 - 72, patient demographics and cost ranges).

22. As per claim 19, Shalmi teaches one or more computer-readable media having computer-executable instructions embodied thereon for performing a method for managing clinically related supply procurement according to outcomes, the method comprising:

- Receiving patient supply data captured from at least one clinically related site, the patient supply data comprising clinical supplies used to treat one or more patients (paragraph 53, manufacturer supply);
- Receiving clinical outcomes data that describes one or more patient outcomes that resulted from using- the clinical from the at least one clinically related site (paragraph 53, patient supply);
- Generating a comparative clinical supply report based at least on the clinical outcomes data (paragraph 53, needs analysis); and
- Storing the comparative clinical supply report in computer accessible memory (paragraph 59).

23. As per claim 20, Shalmi teaches one or more computer-readable media of claim 19 as described above. Shalmi further teaches one or more computer-readable media wherein the patient supply data comprises at least one of surgical device information, pharmaceutical information, and consumable material information (paragraph 53, pharmaceutical information).

24. As per claim 21, Shalmi teaches one or more computer-readable media of claim 19 as described above. Shalmi further teaches one or more computer-readable media wherein the clinically related site comprises at least one of a hospital facility, a research facility and a government facility (paragraphs 52 or 54, hospital).

25. As per claim 22, Shalmi teaches one or more computer-readable media of claim 19 as described above. Shalmi further teaches one or more computer-readable media wherein the clinical outcomes data comprises at least one of patient mortality data, patient morbidity data, patient ambulatory data, patient infection data, patient prescription data, patient length of stay data, patient condition data and patient readmittance data (paragraph 53, patient prescription data).

26. As per claim 23, Shalmi teaches one or more computer-readable media of claim 19 as described above. Shalmi further teaches one or more computer-readable media wherein the comparative clinical supply report comprises at least one historical patient outcome comparison between alternative supply selections (paragraphs 66, 67 and 72, statistical analysis and usage analysis).

27. As per claim 24, Shalmi teaches one or more computer-readable media of claim 23 as described above. Shalmi further teaches one or more computer-readable media wherein the at least one historical patient outcome comparison is based on a combination of at least two supply selections (paragraph 72 – 74, price, time and quantity).

28. As per claim 25, Shalmi teaches one or more computer-readable media of claim 19 as described above. Shalmi further teaches one or more computer-readable media wherein the comparative clinical supply report comprises projected patient outcome comparisons based on

alternative supply selections (paragraph 70 where usage information is kept to determine drug deployment).

29. As per claim 26, Shalmi teaches one or more computer-readable media of claim 25 as described above. Shalmi further teaches one or more computer-readable media wherein the at least one projected patient outcome comparison is based on a combination of at least two supply selections (paragraph 70, location and population or paragraph 71, price and duration or paragraph 72, usage based).

30. As per claim 27, Shalmi teaches one or more computer-readable media of claim 19 as described above. Shalmi further teaches one or more computer-readable media wherein the comparative clinical supply report comprises a report on clinical outcomes data broken down according to at least one of clinical procedure type, clinical department, patient condition categories, patient demographic categories, vendor information and cost ranges (paragraphs 70 - 72, patient demographics and cost ranges).

Response to Arguments

31. Applicant's arguments filed 4/23/2008 have been fully considered but they are not persuasive.

- Independent Claim 1
 - The Applicant states, “the Shalmi reference fails to describe, either expressly or inherently, an ‘interface to receive clinical outcomes data that describes one or more patient outcomes that resulted from using the clinical supplies.’”
 - As the Applicant has not defined what the clinical outcomes may only include, a clinical outcome could be that the result of using a medication

may be a decreased intake of that medication. For example, a person no longer needs antibiotics if the bacterial infection is cured. Therefore, Shalmi tracking of drugs is a clinical outcome from the use of those drugs.

- The Examiner notes that the claims do not require that individual patient outcomes be tracked, as argued, nor do they require information about a specific outcome. General information about a treatment or treatments is therefore enough to satisfy the claimed information from one or more patients and their outcomes.
- The Applicant states, “the Shalmi reference does not describe an ‘analytic engine communicating with the first interface and the second interface to generate comparative clinical supply report based at least on the clinical outcomes data.’”
 - The Applicant's statement that the “Shalmi reference does not consider the result or outcome experience by the patient nor correlate the outcome with supply data” may or may not be true. However, the claimed language does not require this. The claims are for information regarding one or more patients.
 - The intended use of the Applicant's invention is not patentable. A different use of the same invention is anticipatory.
- The Applicant states, “‘patient prescription data’ is not described in the cited section, or any other part, of the Shalmi reference.”
 - The Applicant continues his arguments that narrowly focus on an individual patient's medical outcome. This feature is not claimed.

- Regarding claim 4, the list of data within a database is considered non-functional descriptive information and therefore not given patentable weight.
- Independent claim 10
 - The Applicant has amended claim to include, "wherein the outcome data is patient condition data."
 - The Examiner notes the updated rejection above.
 - As above, the Applicant argues individual patient requirements. This feature is not claimed and therefore these arguments are not persuasive.
- Independent claim 19
 - The Applicant states that claim 19 is "amended herein." The Amendment dated 4/23/2008 does not include an amendment of claim 19.
 - The Applicant repeats the same arguments as above and therefore are not persuasive.
- Regarding further potential amendments, the Examiner suggests review of recent US Supreme Court decisions and those from the Court of Appeals of the Federal Circuit. "The routine addition of modern electronics to an otherwise unpatentable invention typically creates a prima facie case of obviousness. Moreover, there is no pertinent evidence of secondary considerations because the only evidence offered is of long-felt need for the unpatentable mental process itself, not long-felt need for the combination of the mental process and a modern communication device or computer." In re Comiskey, 499 F. 3d 1365, 84 U.S.P.Q. 2d 1670 (Fed. Cir. 2007)

Conclusion

32. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. S./
Examiner, Art Unit 3626
7/17/2008

/Robert Morgan/
Primary Examiner, Art Unit 3626